DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 10, 2015

Dentis Co. Ltd.
c/o Ms. April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, CA 91748

Re: K142313
Trade/Device Name: OneQ-SL Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 3, 2015
Received: November 10, 2015

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142313

Device Name
OneQ-SL Implant System

Indications for Use *(Describe)*
The OneQ-SL Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Submitter
Dentis Co., Ltd.
Sun Chul Shin
#99, Seongseoseo-ro, Dalseo-gu
Daegu city
South Korea
Phone: +82-53-583-2804
Fax: +82-53-583-2806

Official Correspondent
Withus Group Inc.
April Lee
2531 Pepperdale Drive
Rowland Heights, CA 91748
Email: withus6664@gmail.com
Phone: 909-274-9971
Fax: 909-460-8122

Device Information

Trade Name: OneQ-SL Implant System Common
Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 12/09/2015

Description

The OneQ-SL Implant System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.
The OneQ-SL Implant system includes;

- The i-Clean OneQ Fixtures
  Internal Octa-connected, non-submerged fixture

Implant Fixture Dimensions:

Platform Diameter	Implant Nominal (Coronal) Diameter (mm)	Implant Apical Diameter (mm)	Lengths Available (mm)
Regular: Ø 4.8 mm	3.7	3.55	7, 8, 10 ,12, 14
	4.2	3.7	7, 8, 10 ,12, 14
	4.7	4.2	7, 8, 10 ,12, 14
	5.2	4.7	7, 8, 10 ,12, 14
Wide: Ø 6.5 mm	4.2	3.7	7, 8, 10 ,12, 14
	4.7	4.2	7, 8, 10 ,12, 14
	5.2	4.7	7, 8, 10 ,12, 14
	6.0	4.8	7, 8, 10 ,12
	7.0	5.75	7, 8, 10 ,12

The fixture is made of CP Titanium Grade 4. The surface is treated by Sand –blasting (Large grit) and acid etching method (SLA). The Fixtures are supplied sterile.

Indication for Use

The OneQ-SL Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw

retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate devices:

- K120847, ET/SS Implant System manufactured by Osstem Implant Co., Ltd.

	Subject Device	Predicate Device
Device Name	OneQ-SL Regular / Wide Type Fixture	ET/SS Implant System (SSII/III SA Fixture)
510(k) Number	K142313	K120847
Manufacturer	DENTIS CO., LTD.	OSSTEM Implant Co., Ltd.
Intended Use	Mandible and Maxilla Endosseous Dental Implant & Accessories.	Mandible and Maxilla Endosseous Dental Implant & Accessories.
Material	CP Titanium Gr.4	CP Titanium Gr.4
Design (Fixture Type)	 - Internal Octa-connected - Non-Submerged Fixture - Tapered & straight body	 - Internal Octa-connected - Non-Submerged Fixture - Straight & Tapered Body
Platform Diameter(Coronal)	4.8~6.5	4.8~6.0
Fixture Diameter	Regular: Ø 3.7, Ø 4.2, Ø 4.7, Ø 5.2 Wide: Ø 4.2, Ø 4.7, Ø 5.2, Ø 6.0, Ø 7.0	SSII SA Fixture: Ø 4.1-4.9 SSIII SA Fixture: Ø 3.75-5.0
Fixture Length	Regular: 7, 8, 10 ,12, 14 mm Wide: 7, 8, 10 ,12, 14mm 14mm not for all diameters	6~15 mm
Indication for use	The OneQ-SL Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is intended for delayed loading.	ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.
Surface Treatment	SLA	SLA
Gamma Sterilized	Yes	Yes
Product Code	DZE	DZE

Substantial Equivalence Discussion

The OneQ-SL Implant System has a substantially equivalent intended use as the identified predicates. The subject device is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium.
The subject and predicate devices are similar in indications, design, technology, functions, dimensions and materials.

The differences between the subject device and predicate devices are slight differences in fixture's diameters and lengths.

Differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device.

Non-Clinical Test Data
The subject device was tested to evaluate its performance according to the following standards:

- Packaging Test performed in accordance with ISO11607-1:2006 and ISO11607-2:2006
- Sterilization Validation Test performed in accordance with ISO11137-1:2006 and ISO11137-2:2013
- Fatigue Test performed in accordance with ISO14801:2007
- Cytotoxicity Test performed according to ISO 10993-5:2009

Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate device. The result of the above tests have met the criteria of the standard, and proved the substantial equivalence with the predicate device.
Non-clinical testing consisted of performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to the predicate device.

Summary of clinical testing
No additional clinical testing was performed for this submission.

Conclusion
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Dentis Implant Co., Ltd. Concludes that the OneQ-SL Implant System is substantially equivalent to the predicate devices as described herein.